



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95017d

WARNING LETTER

OCT 6 2004

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

Dr. Ronald M. Repice, M.D.
Dr. Ronald M. Repice, II, D.C.
Carpal Kinetics, LLC
1502 Upland Street
Chester, PA 19013

Dear Drs. Repice:

We are writing to you because we have reviewed statements on your firm's website, www.wristrac.com, which indicate that your firm is marketing the Wristrac in the United States for providing traction to the wrist to prevent and to treat acute, sub acute, and chronic Carpal Tunnel Syndrome (CTS), to treat mild, moderate, and severe cases of CTS and other wrist related disorders, and for scar tissue reduction.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), this product is considered a medical device because it is intended for use in the cure, mitigation, treatment, prevention, or diagnosis of a disease or medical condition, or because it is intended to affect the structure or any function of the body. (21 U.S.C. 321 (h)). The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they may offer them for sale. This requirement helps to protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

The Wristrac is stated to provide "a directly controllable traction force across the wrist." www.wristrac.com/wt_background.html. This differs from a limb orthosis, which does not apply traction to the body and as defined in 21 CFR 890.3475 is intended to support, correct, or prevent deformities, or to align body structures for functional improvement. Therefore, it appears that the Wristrac is a nonpowered orthopedic traction apparatus as defined in 21 CFR 888.5850. This type of device has been classified into Class I and is ordinarily exempt from the premarket notification requirement of section 510(k) of the Act. However, under an FDA regulation applicable to this type of device, the exemption from the premarket notification requirement applies only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within the same generic type (i.e., nonpowered orthopedic traction apparatus). The exemption does not apply when the device is intended for a different intended use or operates using a different fundamental scientific technology than a legally marketed device of that generic type." (21 CFR 888.9).

Based on statements made on your firm's website as described above, it appears that your device is intended for different medical uses than other devices of this type that have Class I exempt status. We are unaware of any legally-marketed devices within the same generic type as your firm's product that are intended for treatment of CTS or other wrist disorders. Therefore, your firm's promotion of Wristrac for these medical purposes appears to represent a new

intended use which requires the submission and prior clearance of a premarket notification submission before you may legally market this device for treatment of CTS or other wrist disorders.

We have conducted a review of our files, and have been unable to identify any Food and Drug Administration (FDA) premarket notification clearance number for the Wristac. The kind of information you need to submit in order to obtain this clearance is described in FDA regulations in Title 21 Code of Federal Regulations, Part 807. You may also find the requirements at www.fda.gov/cdrh/devadvice/3122.html. After you submit this information, FDA will evaluate it and decide whether your device may be legally marketed in this country.

Failing to submit a 510(k) as required by the FDA regulations discussed above renders a device misbranded under section 502(o) of the Act, for failure to notify the agency of intent to introduce the device into commercial distribution, as required by section 510(k) of the Act. A review of our records also revealed that your firm has not listed its product as required by section 510(j) of the Act. The failure to comply with this requirement also causes your device to be misbranded under section 502(o). Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that you may legally market your device, your product is also adulterated under section 501(f)(1)(B) of the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective. For a product requiring premarket approval before marketing, the notification required by section 510(k) is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. (21 CFR 807.81(b)).

You should know that these are serious violations of the law and may result in FDA taking regulatory action without any further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, and/or assessing civil money penalties. Also, other federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for your firm to take action on this matter now. Within fifteen (15) working days from the date you receive this letter, please notify this office in writing of the steps you have taken, or will take, to correct the problems described above. We also ask that you explain how you plan to prevent them from happening again. If you need more time, let us know why and indicate when you expect to complete your correction. Please direct your response to:

William MacFarland, Chief
Orthopedic, Physical Medicine & Anesthesiology Devices Branch (HFZ-343)
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Rd.
Rockville, MD 20850

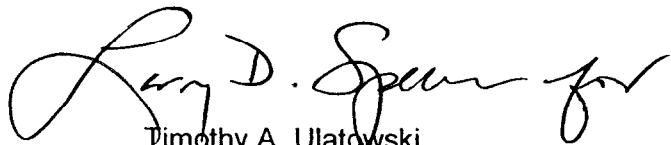
You should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket review for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical

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devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please contact Tracey Bourke at (301) 594-4659.

Sincerely,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is fluid and cursive, with a large initial "T" and a checkmark-like flourish at the end.

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health